



01/19/00

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Washington, D.C. 20231

Attorney Docket No: CV0283a

Date: January 19, 2000

JC564 U.S. PTO

09/487944



Dear Sir:

Transmitted herewith for filing is the patent application of
Inventor(s) : Ronald J. Shannon

For : Method for Determining Care and Prevention Pathways for
Clinical Management of Wounds

THIS APPLICATION CLAIMS THE BENEFIT OF U.S. PROVISIONAL APPLICATION NO.
60/116,349 FILED JANUARY 19, 1999.

Enclosed are :

- ☒ Specification with claims.
☒ 15 sheets of drawing. ☒ Informal.
☐ An assignment of the invention to _____
☐ A certified copy of a _____ application, filed
on _____ under Serial No. _____, the priority of which
is hereby claimed.
☐ A combined declaration and power of attorney.
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☐ Other:

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006110-4462860

**Method for Determining Care and Prevention Pathways for
Clinical Management of Wounds**

5 This application is related to co-pending application number 60/116,349 (filed January 19, 1999), which is incorporated herein by reference in its entirety.

 The present invention relates to methods for consistently designating appropriate treatment protocols for patients, particularly protocols involving wounds or wound prevention.

10 A number of computer programs have been developed wherein a user, for example a care giver, inputs parameters indicative of a patient assessment into a computer and obtains a care plan as an output. Input parameters can include art recognized assessment parameters, such as those recommended by the National Pressure Ulcer Advisory Board. One example of such a computer program is the Wound and
15 Skin Intelligence System (WSIS) developed by Convatec and Applied Health Sciences. Other similar programs have been developed by Johnson & Johnson Medical (a division of Ethicon, Inc.) and Smith & Nephew, Ltd.

 The effective use of such computer-based methods of deriving care plans often requires simultaneous proximity of the care giver to both the patient and the computer.
20 Care givers without ready access to a patient in close proximity to the programmed computer cannot effectively benefit from such computer-based approaches. Moreover, even when the programmed computer is available, the practicalities of providing care often makes it awkward to input data prior to rendering a treatment protocol.

 Accordingly, there is a need for a method of selecting care plans for patients
25 customized to clinical assessment parameters that does not require immediate interaction with a computer, without compromising the quality of care provided. The present invention provides a method for correlating patient assessment parameters with appropriate treatment protocols. The method provides a visually keyed process to derive a care plan. The process does not require a computer, and when executed with a
30 computer is highly integrated with visual cues. Such a process can be embodied in devices that provide bedside tools to assist the care giver to make evidence-based decisions for the care of individuals, such as individuals at risk of forming wounds or individuals who already have wounds, such as a pressure ulcers.

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Summary of the Invention

In one embodiment, the invention relates to a method of identifying a wound care protocol for a given wound or wound prevention protocol appropriate for a given patient comprising: classifying the wound or patient against a defined scale for a first wound factor, which is defined wound assessment factor or defined wound risk assessment factor to obtain a wound classification; grading the wound or patient against defined scales for one or more second wound factors, which are wound assessment factors or wound risk assessment factors; and operating a visual decision tree device to show a decision or visual decision tree corresponding to the wound classification or to a scale for a wound assessment factor, wherein the visual decision tree device identifies at least one component of a treatment protocol for the graded wound factors. In some embodiments, at least one visual decision tree indicates two or more distinct decisions based on the grade of one or more second wound factors. In some embodiments, the visual decision tree is a mechanical device. In some embodiments, the method can also comprise providing an interactive visual scoring sheet on which markers for the available scores for two or more wound factors are displayed; and marking the appropriate score for the two or more wound factors on the interactive visual scoring sheet, wherein the interactive visual scoring sheet contains a marker associated with one or more of the scores identifying an addition to the treatment protocol.

In some embodiments, the invention relates to a method comprising classifying the wound against a defined wound classification scheme; grading the wound against defined scales for one or more second wound assessment factors; and operating visual decision tree device to show a decision or visual decision tree corresponding to the wound classification or to a grade for a wound assessment factor, wherein at least one visual decision tree produced by the device dictates two or more distinct decisions based on the grade of one or more second wound assessment factors, and wherein the visual decision device identifies a treatment protocol for the wound classification and grades of the second wound assessment factors. In some embodiments of the invention, one of the two visual decision tree devices is selected based on wound classification, and the selected visual decision tree device is operated to show a decision or decision tree corresponding to a grade for exudate amount. In some embodiments, the wound

classification scheme grades wounds from non-open or closed wounds, to wounds of various thicknesses, to wounds that cannot be graded due to obstructions.

The invention, in some embodiments, relates to a method of identifying a wound care protocol for a given wound or wound prevention protocol appropriate for a given patient comprising: classifying the wound or patient against a defined scale for a first wound factor, which is defined wound assessment factor or defined wound risk assessment factor to obtain a wound classification; grading the wound or patient against defined scales for one or more second wound factors, which are wound assessment factors or wound risk assessment factors; operating visual decision tree device to show the visual decision tree corresponding to the wound classification or to a scale for a wound assessment factor, wherein at least one visual decision tree dictates two or more distinct decisions based on the grade of one or more second wound factors, and wherein the visual decision tree device identifies at least one component of a treatment protocol for the graded wound factors; and marking a pre-defined display of treatment protocols to identify the components of a treatment protocol identified by the method. In some embodiments, the method of the invention is operated through a graphical user interface on an electronic processor, resulting in a display of treatment protocols that matches a printed display used in manual operations of the method.

The invention also relates to a visual decision tree device for identifying a wound care protocol for a given wound or wound prevention protocol appropriate for a given patient comprising: a mechanical or electronic device for identifying and displaying one of at least two decisions or visual decision trees based on one or more inputted wound factors according to a defined scale, wherein the visual decision tree device identifies at least one component of a treatment protocol for the graded wound factors. In some embodiments, the sliding card comprises markers corresponding to a defined scale for classifying the wound or patient. In some embodiments, one or more sliding cards shows a visual decision tree and wherein the housing comprises a view window through which one or more visual decision trees corresponding to the wound classification can be viewed. In some embodiments, the visual decision tree device is mechanical and wherein the slide card can be moved with respect to the housing to view through the view window any one of a plurality of individual decision trees displayed on the sliding card.

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Brief Description of the Drawings

Figure 1 displays a wound assessment interactive visual scoring sheet.

Figure 2 displays a chronic wound management decision tool, which is a type of portable mechanical slide-rule visual decision tree device.

5 **Figure 2A** displays a schematic of a slide-rule visual decision tree device.

Figure 2B displays a first set of two exemplary sliding cards.

Figure 2C shows a second set of two exemplary sliding cards.

Figure 3 displays a schematic of a modular wound care protocol sheet.

10 **Figure 4** displays a Patient Risk Assessment and Nurse Action Record, which is a type of interactive visual scoring sheet.

Figure 5 displays a Patient Risk Assessment Evaluation Tool, which is a type of portable mechanical slide-rule decision tree device.

Figure 5B displays a third set of two exemplary sliding cards.

Figure 6 displays a modular wound prevention protocol sheet.

15 **Figure 7** displays a Wound Care and Assessment Record.

Figure 8 displays a pressure ulcer pathway decision tool, which is a type of a portable mechanical slide-rule visual decision tree device.

Figure 9 displays a wound assessment interactive visual scoring sheet.

20 **Figure 10** displays a chronic wound management decision tool, which is a type of portable mechanical slide-rule visual decision tree device.

Figure 11 displays a Wound Care and Assessment Record.

Detailed Description of the Invention

FIG. 1 relates to an interactive visual scoring sheet **10** that can be used according to a preferred embodiment of the present invention. The interactive visual scoring sheet **10** can take substantially the same visually-cued form on the screen of a computer or personal device assistant (PDA). In electronic form, each scoring choice is separately on a viewing screen represented as in the paper example illustrated in FIG. 1. The interactive visual scoring sheet **10** comprises a first defined scale **11** for classifying or grading a wound or patient according to a first wound factor **12** and a second defined scale **13** for classifying or grading the wound or patient for one or more second wound factors **14**. In some embodiments, the second defined scale **13** can include classifying or grading of the wound or patient according to: a defined wound assessment factor, a

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defined wound risk assessment factor, some other classification of a patient's condition, or any combination of such factors. The first defined scale **11** and the second defined scale **13** can be represented by one or more markers **19** corresponding to one or more stages, grades or classifications. Markers **19** and associated criteria **15** can be indicated

5 on the visual scoring sheet **10**, for example, by indicia associated with markers **19**, including varying colors, numbers, letters, symbols, texture or any combination thereof. Optional associated criteria is provide a brief indication of the classifying or grading criteria. In some embodiments, the appropriate score for one or more classifying or grading factors can be marked on the interactive visual scoring sheet **10**. The criteria **15**

10 can be indicated in whole or in part on the visual scoring sheet **10**, or be referenced to criteria found elsewhere. The presence of at least a shorthand reference to the criteria is preferred. The second defined scales **13** can be with respect to one or more second wound factors **14**. Second wound factors **14** can, in some embodiments, be selected from any number of factors including but not limited to: exudate amount, necrotic tissue

15 amount, undermining, color of tissue around wound, granulating tissue, peripheral edema, peripheral induration and pain at wound. In some embodiments, second wound factors **14** can include, but are not limited to: sensory perception, moisture, activity, mobility, nutrition and friction & shear. In some embodiments, as shown in FIG. **9**, first wound factors **12** and second wound factors **14** can be selected from the group consisting

20 of: depth, exudate amount, exudate type, necrotic tissue amount, necrotic tissue type, undermining, surrounding skin color, granulation, peripheral edema, peripheral induration, pain at wound, nutrition, infection, edges, epithelization, functional ability, compliance and healthy margin.

The exemplary wound grading factors selected for FIG. **1** are a subset of the

25 exemplary wound grading factors selected for FIG. **9**. The selection of the particular factors of FIG. **1** as sufficient to predict patient care protocols represents an embodiment of the invention.

In some embodiments, one or more of the markers **19** for the first wound factor **12** or second wound factor **14** pertaining to a wound or patient condition can be

30 connected by connecting indicia **16** such as lines or arrows that identify one or more treatment protocol components **17**. One or more treatment protocol components **17** may be correlated to one or more markers **19**, for example by connecting indicia **16**, and may be written or referred to on the interactive visual scoring sheet **10**.

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score on the visual scoring sheet **10** of FIG. 1.

QUESTION 1 (FIG. 2A) identifies which first or second wound factor **12, 14** is used to identify the appropriate marker **19a**. The display of the appropriate marker **19a** aligns the appropriate decision or visual decision tree **18a-18d** in the view window **28**. If present, **QUESTION 2** of the displayed visual decision tree identifies a marker **19b** for which connecting indicia **16b** identify appropriate wound care protocol components **17**. In some instances, such as illustrated decision tree **18c**, the decision tree identifies the wound care protocol component **17** from the marker **19a**.

Wound care protocol components **17** can be grouped in modules on a wound care protocol sheet **30**, as shown in FIG 3. In some embodiments, protocol components **17** for wound care of wound prevention are grouped in alpha-numeric groups or modules **31** that correspond to decision tree **18** outcomes. Based on the decision tree **18** outcomes, one or more protocol components **17** may be followed. The modules **31** can be an alpha-numerically labeled module, can include goals for treatment, multiple alternative therapies and recommended products for treatment.

The schematic of FIG. 2A shows a two part visual decision tree devices **20** comprising a housing **21** and a sliding card **22**. The housing can comprise a top layer **23** and a bottom layer **24** made of, for example, heavy paper or plastic, joined along a top edge **25** and a bottom edge **26**. A view window **28** is cut into the top layer **23**. In some embodiments (not shown in FIG. 2A), the view window can be cut into the top layer or the bottom layer. The sides of the top layer **23** and the bottom layer **24** are left open to allow the sliding card **22** to be inserted and moved within the housing **21**. The top layer **23** can have a question **QUESTION 1** printed on it, which governs where the operator should slide the sliding card **22** so that the appropriate marker from a first set of markers **19a** is indicated in the view window **28**. The sliding card **22** is slid within housing **21** to a position with respect to the view window **28** where the **QUESTION 1** on the top layer **23** is correctly answered by an appropriate marker **19a**. A first set of connecting indicia **16a** (e.g. arrows) points to one or more values for a second set of markers **19b** in response to **QUESTION 2**. The operator selects a value from the second set of markers **19b** in response to a second question **QUESTION 2** found on the sliding card **22** and performs the protocols (referenced as A, B or C in FIG. 2A at the bottom of the sliding card **22**) that are indicated by a second set of arrows **16b**.

In a particular example, the grade on first defined scale **11** on the interactive visual scoring sheet **10** of FIG. 1 identifies whether the slide rule of first housing **21A** or

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the slide rule of second housing **21B** shall be used (FIG. 2). Referring to second housing **21B** of the visual decision tree device **20** of FIG. 2, the score for alpha second defined scale **13a** identifies the position to which the ruler is adjusted. Referring to first and second sliding cards **22a**, **22b** of FIG. 2 and FIG. 2C, in the first sliding card **22a**, one dialed position (e.g., “0” on defined scale **13a** for first sliding card **22a** of FIG. 2C) gives a wound care protocol component **17** depending on the score of beta second defined scale **13c**. Another dialed position (e.g., “2” on defined scale **13a** for second sliding card **22b** of FIG. 2C) depends on the score of delta second defined scale **13d**. Two dialed positions (e.g., “1” or “3” on defined scale **13a** for first sliding card **22a** of FIG. 2C) directly indicate wound care protocol components **17**. Some dialed positions on the second sliding card depend on gamma second defined scale **13b**. Referring to FIG. 1, additional wound care protocol components **17** are identified on the visual scoring sheet **10** by connecting indicia **16** associated with first defined scale **11** and beta, epsilon, zeta, eta and theta wound care protocol components **13B**, **13E-13H** (FIG. 1). Shown in FIGs. **2B** and **2C** are particular exemplary first slide and second slide cards **22c**, **22d** and **22a**, **22b**, (respectively). Some embodiments, for example as shown in FIG. 5 and FIG. 5B, can have a third sliding card **22e** and a fourth sliding card **22f** which can slide independently of each other to align a first marker **19a** or a second marker **19b** with a first view window **28a** and a second view window **28b**, respectively. These exemplary slide cards are shown in FIGs **5B** and **5C**, respectively.

FIG. 2B and FIG. 2C display exemplary sets of first and second sliding cards 22a, 22b which can be used to practice the invention. The sliding cards 22a, 22b include separate visual decision trees 18e-18l that can be aligned with a view window of a housing. Likewise, FIG. 2C displays a set of first and second sliding cards 22a and 22b that include visual decision trees 18m-18t. For example, the first and second sliding cards 22c, 22d of FIG. 2B can be used in the visual decision tree device 20 of FIG. 10. Likewise, the first and second sliding cards 22a, 22b of FIG. 2C can be used in the visual decision tree device 20 of FIG. 2. In FIG. 2B, first and second sliding cards 22c, 22d have markers 19a that correspond to a first defined scale 13a and markers 19b that correspond to one or more second defined scales 13b, 13c, 13d. Similarly, first and second sliding cards 22a, 22b of FIG. 2C have a first set of markers 19a corresponding to a first defined scale 13a, a second defined scale 13b, a third defined scale 13c and a fourth defined scale 13d, which scales are defined for this example in the interactive

visual scoring sheet **10** of FIG. 1. The example displayed in FIG. 2C can be used in the visual decision tree device **20** of FIG. 2.

In preferred embodiments, a patient data sheet **40** can be combined with an interactive visual scoring sheet **10** and a wound care protocol sheet **30** in a patient care
5 into a patient diagnostic tool which can be, for example, a single double sided folder or folded sheet of paper. The patient diagnostic tool can be used in conjunction with one or more visual decision tree devices **20**.

The invention can comprise any number of embodiments, some of which are described in the Figures. In some embodiments of the invention, the interactive visual
10 scoring sheet can have different first defined scale **11** and different second defined scale **12** for wound classifying or grading or patient risk assessment. FIG. 1, FIG. 4 and FIG. 9 show different visual scoring sheets **10** that can be used to practice the invention. FIG. 2, FIG. 5, FIG. 8 and FIG. 10 show different visual decision tree devices **20** that can be used to practice the invention. FIG. 3 and FIG. 6 show different wound care protocol
15 sheets **30** that can be used to practice the invention. FIG. 7 and FIG. 11 show different patient data sheets **40** that can be used to practice the invention. The figures are provided as examples of possible embodiments of elements which may be used to practice the invention, and should not be construed to limit the scope of the invention.

20 Definitions

The following terms shall have, for the purposes of this application, the respective meaning set forth below.

- **interactive visual scoring sheet.** An interactive visual scoring sheet is printed or
25 electronic sheet on which scoring choices of wound factors are displayed in a form in which the scores can be visually marked.
- **matching electronic display.** An electronic display of treatment protocols matches a traditionally printed display if the treatment options displayed match.
- **slide rule device.** A mechanical visual decision tree device, which can include, for
30 example, a slide rule or slide wheel device.

• **visual decision tree.** A visual decision tree is a representation of two or more decisions, with the appropriate decision indicated visually based on the score of at least one wound factor.

- **visual decision tree device.** A visual decision tree device is a device, electrical or mechanical, which can provide a visual image of a decision or decision tree based on an inputted wound care or wound prevention assessment value. The device produces two or more separate visual images of a decision or decision tree, including at least one decision tree depending on the input value. With a mechanical device, such as a slide rule or slide wheel, “inputting” comprises adjusting the mechanical device to correspond to the input value.
- **wound factor.** A wound factor is a wound assessment factor for which there is a defined grading scale or a wound risk assessment factor for which there is a defined grading scale.

- The following examples further illustrate the present invention, but of course, should not be construed as in any way limiting its scope.

Example 1 - Wound Treatment

- One example of a method for assessing the status of a patient and derivation of a care plan, or protocol, for wound treatment is as follows. A front cover of a Wound Care & Assessment Record (FIG 7) can be completed and included to identify the patient and care giver and to record dates and details of treatment, or the like. A Wound Assessment Record (Pressure Sore Status Tool), a type of interactive visual scoring sheet (FIG. 1) is completed by circling appropriate assessment scores for each factor (exudate amount, necrotic tissue amount, undermining, surrounding skin color, granulation, peripheral edema, peripheral induration, and pain). Using the interactive visual scoring sheet of FIG. 1, a care giver, upon examining a wound, classifies the wound as Stage 3 according to the first defined scale for classification. The care giver then assigns the following scores to assessing the wound according to their respective second defined scale for grading the wound: Exudate amount = 3; Necrotic Tissue Amount = 3; Undermining = 2; Color of Tissue Around Wound = 3; Granulating Tissue = 3; Peripheral Edema = 1; Peripheral Induration = 0; Pain at Wound = 4.

Next, the Chronic Wound Management Pathway Decision Tool, a type of portable mechanical slide-rule visual decision tree device, of FIG. 2 is used as follows: (i) using the Exudate Amount score selected from the interactive visual scoring sheet of FIG. 1, go to the colored side of the slide rule recommended; (ii) from the interactive visual scoring sheet of FIG. 1, identify the score checked for exudate amount and move the slide rule to the score for exudate amount; (iii) follow the arrows, answer all questions and select the appropriate nurse action items; (v) circle the numbers in the Nurse Action Report (Care Plan), a type of modular wound care protocol (FIG. 3).

Accordingly, the care giver having assessed the wound, follows the decision tree provided in FIG. 1 and FIG. 2 to arrive at a care plan from FIG. 3. Following the wound assessment data detailed in the above example, this process is as follows. First, the caregiver notes that the marker for Stage 3 in the Classification of Wound scale has two arrows connected to it: a vertical arrow (which points to "See Red Side of Nurse Action Guide") and a horizontal arrow that passes through the marker pointing from left to right (which points to "Nurse Action 5"). The vertical arrow requires the care giver to consult the red side of the decision tool (i.e. Nurse Action Guide), which corresponds to the top section of FIG. 2. Beginning at "START HERE" in the upper portion of the tool represented in FIG. 2, the care giver slides the card in the housing so that the number determined for Exudate Amount in the wound assessment is showing (i.e. "3" in the example). Once this is done, an arrow on the sliding card points to Nurse Actions 2 and 2C, which are found in FIG. 3, with accompanying text in Sections 2 and 2A of Table 1. The care giver then follows the protocols corresponding to Nurse Actions 2 and 2C.

Returning to the interactive visual scoring sheet of FIG. 1, the care giver next visually notes all factors indicated that are intersected by a line with an arrow attached as an endpoint (necrotic tissue amount, surrounding skin color, granulation, peripheral edema, peripheral induration, pain at wound and nutrition). If a line attached to the box is checked or circled then the care giver follows through to the end of the arrow where one finds the appropriate nurse action referenced. The care giver then records the nurse action on the modular wound care protocol (e.g., Nurse Action Report (Care Plan) of FIG. 3) by circling it. If a checked or circled box or marker does not have a line attached to it then the care giver is not required to do anything further for that marker. Finally, after circling all numbers on the modular wound care protocol (e.g. FIG. 3), the care giver follows the care plan and proceeds to take action.

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Returning to the visual scoring sheet results in the above example, the horizontal arrow horizontally intersecting marker 3 for classification of wound and pointing to “Nurse Action 5” indicates that the care giver should also perform Nurse Action 5 (which is found in Section 5 of Table 1).

- 5 Next, the care giver can examine each marker indicated in the grading scales (from “Exudate Amount” down to “Pain @ Wound”) and look for horizontal arrows passing through a marker. For instance, the marker for “3” indicated for “Necrotic Tissue Amount” has an arrow pointing to “Nurse Action 3”. Accordingly, the care giver would then perform the protocol for Nurse Action 3 (found in FIG. 3, with text in
- 10 Section 3 of Table 1). The results indicated above for “Granulating Tissue” (3) and “Peripheral Edema” (1) both require Nurse Action 4, however such multiple indications for any given Action do not increase the number of times the Action must be performed (i.e. in this example, Nurse Action 4 is performed once, not twice). Finally, the marker for “Pain @ Wound” (4) intersects an arrow that points to Nurse Action 6. Thus, in
- 15 following the example above, the care giver would circle and perform Nurse Actions 2, 2C, 3, 4, and 5 as indicated in FIG. 3 by circles 32.

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Table 1: Possible text for modular wound care protocol Sheet (FIG. 3)

Table 1, SECTION 1	
1	<p>*GOAL* Maintain intact skin: Beware of deep tissue damage that may be irreversible.</p> <p>Assess knowledge of patient/caregiver on risk of skin breakdown and methods of prevention.</p> <p>Reduce effect of risk factors.</p> <p>Pressure: regular repositioning and pressure distribution (pillows, devices)</p> <p>Shear/friction: Apply protective ointment or moisture retentive dressing to reduce friction</p> <p>Excess Moisture: Clean at routine intervals with a skin cleanser, pat dry. Protect skin from moisture and irritants with a moisture barrier and/or absorbent dressings/absorbent products.</p> <p>Dryness: Follow routine bathing procedure with gentle cleansers. Moisturize immediately after bathing. Apply body cream for areas prone to extreme dryness.</p> <p>Trauma/Skin Tears: Apply protective coverings to protect against friction and/or pressure</p> <p>Nutrition altered: Nutritional Support</p> <p>Action Taken _____</p> <p>SKIN CARE PRODUCTS:</p> <p>Patient Bathing</p> <p><input type="checkbox"/> Aloe Vesta 2-n-1 Body Wash/Shampoo <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Sensi-Care Perineal/Skin Cleanser <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Aloe Vesta 2-n-1 Skin Perineal/Skin Cleanser <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Other _____ <i>Days Used</i> M T W T F S S</p> <p>Moisture Barriers</p> <p><input type="checkbox"/> Aloe Vesta 2-n-1 Protective Ointment <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Sensi-Care Protective Barrier <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Other _____ <i>Days Used</i> M T W T F S S</p> <p>Skin Moisturizers</p> <p><input type="checkbox"/> Aloe Vesta 2-n-1 Skin Conditioner <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Sensi-Care Protective Barrier <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Other _____ <i>Days Used</i> M T W T F S S</p> <p>Moisture Retentive Dressings</p> <p><input type="checkbox"/> DuoDERM Extra Thin Size _____ <i>Days Used</i> M T W T F S S</p> <p>Absorbent Dressings</p> <p><input type="checkbox"/> Lyofoam Size _____ <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Hydrosorb Size _____ <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Other Size _____ <i>Days Used</i> M T W T F S S</p> <p>Protective Coverings</p> <p><input type="checkbox"/> Tubifast <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Tubipad <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Arthropad <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Other _____ <i>Days Used</i> M T W T F S S</p>

Table 1, SECTION 2	
2	*GOAL* Obtain a clean wound bed.
PRODUCTS: <u>Wound Cleansing</u> <input type="checkbox"/> SAF Clens <i>Days Used</i> M T W T F S S <input type="checkbox"/> Other _____ <i>Days Used</i> M T W T F S S	
2A	*GOAL* Provide moist wound environment.
PRODUCTS: <u>Primary Dressing</u> <u>Moisture Retentive Dressing</u> <input type="checkbox"/> DuoDERM CGF Size _____ <i>Days Used</i> M T W T F S S <input type="checkbox"/> Other _____ Size _____ <i>Days Used</i> M T W T F S S <u>Secondary Dressing</u> Not applicable.	
2B	*GOAL* Assist in autolytic debridement and removal of necrotic tissue / Provide moist wound environment.
PRODUCTS: <u>Primary Dressing</u> <u>Wound Hydration</u> <input type="checkbox"/> DuoDERM Hydroactive Gel <i>Days Used</i> M T W T F S S <input type="checkbox"/> Other _____ <i>Days Used</i> M T W T F S S	
PRODUCTS: <u>Primary Dressing</u> <u>Exudate Management</u> <input type="checkbox"/> AQUAGEL Hydrofiber Size _____ <i>Days Used</i> M T W T F S S <input type="checkbox"/> Kaltostat Size _____ <i>Days Used</i> M T W T F S S <input type="checkbox"/> Lyofoam Foam Dressing Size _____ <i>Days Used</i> M T W T F S S <input type="checkbox"/> Other _____ <i>Days Used</i> M T W T F S S <u>Secondary Dressing</u> <u>Moisture Retentive Dressing</u> <input type="checkbox"/> DuoDERM CGF Size _____ <i>Days Used</i> M T W T F S S <input type="checkbox"/> Other _____ Size _____ <i>Days Used</i> M T W T F S S	

Table 1, SECTIONS 3 AND 4	
3	<p style="text-align: center;">*GOAL* Reduce devitalized tissue.</p> <p>PRODUCTS:</p> <p>Debridement The suggested topical treatments will facilitate autolytic debridement. Autolytic debridement is usually not recommended for patients with infected wounds or patients at increased risk of infection.</p> <p> <input type="checkbox"/> Surgical by <input type="checkbox"/> MD <input type="checkbox"/> Nurse <input type="checkbox"/> Enzymatic Days Used M T W T F S S <input type="checkbox"/> Autolytic <input type="checkbox"/> Mechanical Products Used _____ _____ _____ </p>
4	<p style="text-align: center;">*GOAL* Identify infection and institute medicine treatment.</p> <div style="display: flex;"> <div style="flex: 1; padding-right: 10px;"> <p>If infection is confirmed, perform Nurse Action 4A. If infection is not confirmed, perform Nurse Action 4B.</p> <p>Nurse Action 4A: Appropriate medical treatment for infection should be initiated or continued. DuoDERM CGF dressings can be continued during the treatment of infection at the discretion of the clinician.</p> <p>Nurse Action 4B: Evaluate for signs of infection. If not infected, moisture retentive dressing should extend beyond reddened area to protect skin.</p> <p>Minimize friction and shear forces to surrounding skin.</p> <p>Action Taken and Products Used to Treat Infection _____ _____ _____</p> </div> <div style="flex: 1; padding-left: 10px;"> <p>PRODUCTS:</p> <p><u>Primary Dressing</u> <i>Wound Hydration</i> <input type="checkbox"/> DuoDERM Hydroactive Gel Days Used M T W T F S S <input type="checkbox"/> Other _____ Days Used M T W T F S S</p> <p><u>Secondary Dressing</u> <i>Moisture Retentive Dressing</i> <input type="checkbox"/> DuoDERM CGF Size _____ Days Used M T W T F S S <input type="checkbox"/> Other _____ Size _____ Days Used M T W T F S S</p> </div> </div>

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Table 1, SECTIONS 5 AND 6	
5	*GOAL* .Prevent further skin breakdown and stimulate healing.
Relieve pressure PRESSURE ULCER --institute turning schedule for patient --utilize pressure reduction device(s) Action Taken and Products Used _____ _____	
<input type="checkbox"/> Bed/Mattresses _____ <input type="checkbox"/> Devices _____ <input type="checkbox"/> Other _____	
VENOUS STASIS ULCER Compression Therapy (30-40mm/Hg pressure to heal ulcer)	
PRODUCTS: <input type="checkbox"/> SurePress™ High Compression Bandage <input type="checkbox"/> SurePress Absorbent Padding <input type="checkbox"/> UNNA-FLEX <i>Days Used</i> M T W T F S S	
DIABETIC FOOT ULCERS Off loading of pressure	Action Taken and Products Used _____ _____
6	*GOAL* Pain Management
Provide analgesics. Cover with Moisture Retentive Dressings. Action Taken and Products Used _____ _____	

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Table 2: Possible text for modular wound care protocol Sheet (FIG. 3)

Nurse Action Report (Care Plan) Circle or check off the appropriate treatments and indicated products used.

5

Solutions for Wound Treatment

Table 2, SECTION 1	
1	<p>*GOAL* Maintain intact skin: Beware of deep tissue damage that may be irreversible.</p> <p>Assess knowledge of patient/caregiver on risk of skin breakdown and methods of prevention.</p> <p>Reduce effect of risk factors.</p> <p>Pressure: regular repositioning and pressure distribution (pillows, devices)</p> <p>Shear/friction: Apply Skin Care products (lubricate) <i>or</i> Moisture Retentive Dressing (reduce friction)</p> <p>Excess Moisture: Manage with Skin Care Products or Moisture Retentive Dressing (protection) and incontinence products</p> <p>Dryness: Use Skin Care bathing and protection products.</p> <p>Nutrition altered: Nutritional Support</p> <p>Action Taken _____</p> <p>_____</p>
	<p>PRODUCTS:</p> <p>Patient Bathing</p> <p><input type="checkbox"/> Aloe Vesta Body Wash/Shampoo <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Septi-soft Body Wash/Shampoo <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Other _____ <i>Days Used</i> M T W T F S S</p> <p>Skin Protection</p> <p><input type="checkbox"/> Aloe Vesta Skin Cream <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Aloe Vesta Protective Ointment <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Other _____ <i>Days Used</i> M T W T F S S</p> <p>Incontinence Care</p> <p><input type="checkbox"/> Aloe Vesta Antifungal Ointment <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Aloe Vesta Protective Ointment <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Aloe Vesta Perineal Foam <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Aloe Vesta Perineal Solution <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Ilex Skin Protectant Paste <i>Days Used</i> M T W T F S S</p> <p><input type="checkbox"/> Other _____ <i>Days Used</i> M T W T F S S</p>

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Table 2, SECTIONS 2 and 3 - Debride Necrotic Tissue

2	Debride necrotic tissue.	
3	*GOAL* Provide systematic support/preventive measures to facilitate healing based on general patient assessment findings	
3	Wound Cleansing.	3A Moisture Retention
PRODUCTS: <input type="checkbox"/> Saline <i>Days Used</i> M T W T F S S <input type="checkbox"/> SAF Clens <i>Days Used</i> M T W T F S S <input type="checkbox"/> Other <i>Days Used</i> M T W T F S S		Primary Dressing: PRODUCTS: <input type="checkbox"/> DuoDERM CGF <i>Days Used</i> M T W T F S S <input type="checkbox"/> DuoDERM Extra Thin <i>Days Used</i> M T W T F S S <input type="checkbox"/> Signadress <i>Days Used</i> M T W T F S S <input type="checkbox"/> Other <i>Days Used</i> M T W T F S S Secondary Dressing: N/A
3B	Wound Hydration	3C Exudate Management
Primary Dressing: <i>Wound Hydration:</i> PRODUCTS: <input type="checkbox"/> DuoDERM Hydroactive CGF <i>Days Used</i> M T W T F S S <input type="checkbox"/> SAF Gel <i>Days Used</i> M T W T F S S <input type="checkbox"/> Other <i>Days Used</i> M T W T F S S Secondary Dressing: <i>Moisture Retentive Dressing:</i> PRODUCTS: <input type="checkbox"/> DuoDERM CGF <i>Days Used</i> M T W T F S S <input type="checkbox"/> DuoDERM Extra Thin <i>Days Used</i> M T W T F S S <input type="checkbox"/> Signadress <i>Days Used</i> M T W T F S S <input type="checkbox"/> Other <i>Days Used</i> M T W T F S S		Primary Dressing: <i>Exudate Management:</i> PRODUCTS: <input type="checkbox"/> Aquacel Hydrofiber <i>Days Used</i> M T W T F S S <input type="checkbox"/> Kaltostat Dressing <i>Days Used</i> M T W T F S S <input type="checkbox"/> Carboflex Odor <i>Days Used</i> M T W T F S S <input type="checkbox"/> Other <i>Days Used</i> M T W T F S S Secondary Dressing: <i>Moisture Retentive Dressing:</i> PRODUCTS: <input type="checkbox"/> DuoDERM CGF <i>Days Used</i> M T W T F S S <input type="checkbox"/> DuoDERM Extra Thin <i>Days Used</i> M T W T F S S <input type="checkbox"/> Signadress <i>Days Used</i> M T W T F S S <input type="checkbox"/> Other <i>Days Used</i> M T W T F S S

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Table 2, SECTIONS 4, 5, 6, and 7			
4	*GOAL* Reduce devitalized tissue.		
<p>Debridement: The suggested topical treatments will facilitate autolytic debridement. Autolytic debridement is usually not recommended for patients with infected wounds or patients at increased risk of infection.</p> <p> <input type="checkbox"/> Surgical by <input type="checkbox"/> MD <input type="checkbox"/> Nurse <input type="checkbox"/> Enzymatic Days Used M T W T F S S <input type="checkbox"/> Autolytic <input type="checkbox"/> Mechanical Products Used _____ _____ </p>			
5	If infection is confirmed, perform Nurse Action 5A. If infection is not confirmed, perform Nurse Action 5B.		
5A		5B	
Appropriate medical treatment for infection should be initiated or continued. DuoDERM CFG dressings can be continued during the treatment of infection at the discretion of the clinician.		Evaluate for signs of infection. If not infected, moisture retentive dressing should extend beyond reddened area to protect skin. Minimize friction and shear forces to surrounding skin.	
Action Taken and Products Used to Treat Infection _____ _____ _____			
6	Relieve Pressure	7	Provide analgesics. Cover with Moisture Retentive Dressings.
Action Taken and Products Used _____ _____ _____		Action Taken and Products Used _____ _____ _____	

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followed. Table 3 provides the text of protocols that can be arranged on a single wound prevention protocol sheet, as shown schematically in FIG. 6.

The method of practicing the invention is outlined in the example below. The care giver obtains the Patient Risk Assessment Record (FIG. 4) and the Slide Rule Pressure Ulcer Pathway Decision Tool of FIG. 5, and then examines a patient. The care giver obtains the following assessments: Sensory Perception = 3; Moisture = 1; Activity = 2; Mobility = 2; Nutrition = 4; Friction & Shear = 3. After recording this assessment on the Patient Risk Assessment Record (FIG. 4), the care giver follows any arrows in FIG. 4. Specifically, the Moisture grading of 1 points to "See Moisture Chart", the Activity grading of 2 points to "See Activity Chart", the Nutrition grading of 4 has no arrows and the Friction & Shear grading of 3 has no arrows.

The care giver then uses the Slide Rule Pressure Ulcer Pathway Decision Tool of FIG. 5, and follows the decision tree for moisture. The first and second sliding cards 22e, 22f of FIG. 5 are displayed in FIG. 5B. Answering all questions, the care giver performs all nurse actions that apply. For instance, if the patient does not suffer urinary or fecal incontinence, but does perspire the care giver would perform Nurse Action F, but not nurse actions A, B, C, D, or E. Further consulting FIG. 5, the care giver slides the sliding card to an Activity rating of 2 and follows the arrows and protocols indicated in the view window (namely Nurse Action K, but not Nurse Action J since the Braden Scale total score is 15 for this patient). The care giver then slides the sliding card until the grade of 3 for nutrition number is indicated in the view window. The care giver then follows protocols indicated in the Nutrition window. For the patient above, given that the patient is only fed orally, Nurse Action P would be performed by the care giver, but not Nurse Actions O or V. The care giver then consults the Friction and Shear section of FIG. 5. Noting that a score of 3 for Friction & Shear does not appear with any arrows, no further Nurse Action protocols need be performed. Thus, for the patient of this example, as shown in the Nurse Action Report Sheet (FIG. 6), Nurse Action protocols F, K and P should be performed by the care giver.

Table 3: Possible text for modular wound prevention protocol sheet (FIG. 6)**Nurse Action Report**

Circle or check off the appropriate treatments and indicate products

used.

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Table 3, Section 1: Managing Moisture

A. If related to tube feeding, lower volume, increase delivery time, decrease osmolality, add filler or add bulking agent. (*Consult dietary plan*). If nutritional intake is entreal, determine potential causes of loose stool. Check for impaction. If frequent, apply fecal incontinence pouch. If persistent, obtain order for anti-diarrheal medication.

☐ Products used

B. Cleanse skin promptly and thoroughly with incontinence skin cleanser or non-drying soap and pat dry.

☐ Aloe Vesta Perineal Solution
☐ Aloe Vesta Perineal Foam
☐ Other _____

C. If taking diuretic, schedule in late afternoon. If moisture is due to regular nighttime urinary incontinence, consider one scheduled toileting during the night.

D. Implement q 2h toileting schedule (waking hours) and offer fluids every 2 hours during waking hours. Cleanse skin promptly with non-drying soap or incontinence skin cleanser, pat dry. Use moisture barrier to protect skin. Use only underpads that wick fluid away from the skin, leaving surface next to skin dry. Cleanse skin, incontinence cleanser or non-drying soap.

☐ Aloe Vesta Perineal Solution
☐ Aloe Vesta Perineal Foam
☐ Aloe Vesta Protective Ointment
☐ Other _____

E. Use moisture barrier to protect surrounding tissue. Pouch heavily draining wound (Consult ET).

☐ Aloe Vesta Protective Ointment
☐ Other _____

F. Check linens every two hours. Change linens as needed. Bathe daily to remove waste products left by perspiration. Clean skin folds thoroughly, but gently and pat dry. Consider different mattress or support surface if a non-breathable covering is aggravating problem.

☐ Septi Soft Body Wash & Shampoo
☐ Other _____

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Table 3, Section 2: Activity

G. Implement plans for small shift in position.

H. Use pressure reducing chair seating. Implement q 1h chair repositioning schedule.

☐ Positioning Cushion

I. Teach patient to do lift-off's 15 minutes.

J. When in bed, use foam wedges for lateral position and pillow to bridge sacrum. Avoid lateral positioning of more than 30 degrees.

☐ Positioning Cushion
☐ Pillow
☐ Other _____

K. Place pressure reducing surface on bed or chair. Avoid positioning directly on trochanter.

☐ Mattress Overlay
☐ Positioning Cushion
☐ Other _____

L. When in bed, use positioning devices to suspend heels so they do not touch the mattress. Use good positioning to keep knees from touching. Avoid elevating HOB more than 30 degrees, except for brief periods.

☐ Positioning Cushion
☐ Other _____

M. Use pressure reducing chair seating. Implement q 1h chair repositioning schedule.

☐ Positioning Cushion
☐ Other _____

N. Implement q 2h turning schedule. If patient can make purposeful movements, encourage frequent turning/shifts in body position.

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Table 3, Section 3: Managing Nutrition

O. If dietician was not consulted to determine the match between the patient condition, metabolic need, and formula type and amount - initiate dietary consult to do so now.

P. Give protein supplement at bedtime.

☐ Protein Supplement

Q. If the patient is receiving less than optional amount because of high residual volumes in stomach, notify physician and obtain medication orders to decrease gastric retention or obtain orders for parental nutrition.

If the patient is receiving less than the optimal amount because of inadequate ordering or changes in patient's condition, request new orders from physician or dietician.

R. Request order for multi-vitamin with Vitamins A, C, and Zinc. Obtain dietary consult if these interventions are not successful within 24 hours. Change diet to reflect food preferences/habits or to address any problems with chewing or swallowing. Create caloric intake plan and monitor goal achievement.

☐ Vitamin Supplement

S. Attempt protein supplement at meals and before bedtime.

☐ Protein Supplement

T. Give supplement twice a day.

☐ Protein Supplement

☐ Other _____

U. Initiate physician contact to clarify goals of treatment and/or to examine avenues to improve nutritional intake.

V. Reassess periodically if patient's condition changes.

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Table 3, Section 4: Friction & Shear

W. Avoid raising HOB>30 degrees.
Use lifting sheet to move patient in bed; do not drag patient across the linens. Use elbow and heel protectors if these prominences are exposed to friction. Use a sheepskin under spastic extremities. (Do not place under trunk.)

- ☐ Positioning Cushion
☐ Heel or Elbow Protectors

X. Consider a trapeze, if patient has sufficient upper body strength to assist in moves.

Patient_____

Date:_____

Nurse_____

Physician_____

Notes_____

Further information for products referred to in the above table is listed below.

5

- AQUACEL Hydrofiber: a wound dressing comprising a non-woven pad composed of sodium carboxymethylcellulose fibers. The dressing is highly absorbent and forms a soft gel interacts with wound exudate and forms a soft gel which maintains a moist environment for wound healing.

10

- Arthropad: Tubigrip Arthropad is a wrapping bandage designed to provide lasting, effective support with complete freedom of movement for the patient. The Tubigrip Arthropad provides tissue support in the management of soft-tissue injuries and general edema and may be used as a pressure dressing.

15

- Carboflex Odor: A sterile non-adhesive dressing with an absorbent wound contact layer (containing Alginate and Hydrocolloid), an activated charcoal pad and a smooth water-resistant top layer.

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- DuoDERM Extra Thin: highly flexible, control gel formula dressing made for use on dry to lightly exuding wounds. The dressing conforms to the body,

cleans by autolytic debridement and is a highly effective secondary dressing for wound fillers.

- DuoDERM Hydroactive Gel: a sterile gel comprising natural hydrocolloids (pectin, sodium carboxymethylcellulose) in a clear, viscous vehicle.
- DuoDERM Hydroreactive Gel: a sterile gel composed of natural hydrocolloids (pectin, sodium carboxymethylcellulose) in a clear, viscous vehicle. This product is designed for the management of partial and full-thickness wounds and creates a moist healing environment around a wound which helps to promote the natural autolytic process of debridement.
- DuoDERM CGF: is a dressing that interacts with wound exudate to produce a soft mass that enables removal of the dressing with little or no damage to newly formed tissues. The dressing helps isolate the wound against bacterial, viral (HIV-1 and HBV) and other external contamination and can remain in place up to seven days.
- Kaltostat: a sterile non-woven dressing of calcium-sodium alginate fiber which can absorb wound exudate or saline and convert from a firm gel/fiber mat. The gel forms a moist, warm environment at the wound interface.
- Kalostat Dressing: a highly absorbent calcium alginate dressing derived from natural seaweed designed to absorb exudate and control minor bleeding. The dressing is easy to apply, can remain in place up to seven days, and may be used on moderately to heavily exuding wounds.
- Lyofoam Foam Dressing: A polyurethane foam dressing comprising an absorptive hydrophilic contact surface and a secondary outer foam layer through which the aqueous component can be lost by evaporation. The dressing is freely permeable to gases and water vapor but resists strike-through of aqueous solutions and exudate, as the outer layer has hydrophobic properties.
- SAF Gel: an alginate containing formulation designed for multiple uses. The gel is indicated for use on chronic and acute wounds such as dry wounds, pressure ulcers (Stages I to IV) and stasis ulcers.
- SAF Clens: a wound cleaner that has a dual surfactant formulation designed for cleansing of chronic wounds, including superficial, partial-thickness, dry or necrotic wounds. The wound cleanser is nontoxic, nonirritating and comes in no-rinse formula.
- Signadress: a hydrocolloid dressing comprising an inner (wound contact) layer of hydrocolloids contained within an adhesive polymer matrix and an outer layer of polyurethane film. The dressing also has a product identification mark (ConvaTec registered tear drop trademark) and a visible (SignaDRESS) change indicator guide printed on the film backing.

- Sure Press High Compression Bandage and Sure Press Absorbant Padding: The SurePress High Compression Bandage System is comprised of two layers: the SurePress High Compression Bandage, a washable bandage made from high-quality blend of cotton-viscose, nylon and LYCRA, and the SurePress Absorbent Padding for use as an underlayer. The System can be used for management of venous leg ulcers and associated conditions, and is contraindicated for the management of arterial and mixed venous/arterial ulcers and legs with an ankle circumference less than 18 cm.
- Tubipad: is made from a layer of polyurethane foam banded to a length of elastic tubular bandage that is used for the protection of heels, elbows and knees.
- UNNA-FLEX: is an elastic bandage that provides compression, for instance to improve venous return. The bandage can be self-adherent or in the form of a boot.

One will appreciate that products listed in the table above, or functional equivalents, are commercially available from a variety of vendors.

- All publications and references, including but not limited to patents and patent applications, cited in this specification are herein incorporated by reference in their entirety as if each individual publication or reference were specifically and individually indicated to be incorporated by reference herein as being fully set forth. Any patent application to which this application claims priority is also incorporated by reference herein in its entirety in the manner described above for publications and references.

- While this invention has been described with an emphasis upon preferred embodiments, it will be obvious to those of ordinary skill in the art that variations in the preferred devices and methods may be used and that it is intended that the invention may be practiced otherwise than as specifically described herein. Accordingly, this invention includes all modifications encompassed within the spirit and scope of the invention as defined by the claims that follow.

What is claimed:

1. A method of identifying a wound care protocol for a given wound or wound prevention protocol appropriate for a given patient comprising:
classifying the wound or patient against a defined scale for a first wound factor,
5 which is defined wound assessment factor or defined wound risk assessment factor to obtain a wound classification;
grading the wound or patient against defined scales for one or more second wound factors, which are wound assessment factors or wound risk assessment factors;
and
10 operating a visual decision tree device to show a decision or visual decision tree corresponding to the wound classification or to a scale for a wound assessment factor, wherein the visual decision tree device identifies at least one component of a treatment protocol for the graded wound factors.

2. The method of claim 1, wherein the visual decision tree is a mechanical device.

3. The method of claim 1, wherein at least one visual decision tree indicates two or more distinct decisions based on the grade of one or more second wound factors.

4. A method of claim 1 of identifying a wound care protocol appropriate for a given wound comprising:

classifying the wound against a defined wound classification scheme;

grading the wound against defined scales for one or more second wound

assessment factors; and

operating visual decision tree device to show a decision or visual decision tree corresponding to the wound classification or to a grade for a wound assessment factor, wherein at least one visual decision tree produced by the device dictates two or more distinct decisions based on the grade of one or more second wound assessment factors,
and wherein the visual decision device identifies a treatment protocol for the wound classification and grades of the second wound assessment factors.

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20

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A B S T R A C T

The present invention relates to methods for consistently designating appropriate treatment protocols for patients, particularly protocols involving wounds or wound prevention. Specifically, the invention relates to methods wherein a patient condition such as a wound is assessed against defined scales for classifying and grading, which assessment is used in a visual decision tree device to identify one or more components of a treatment protocol.

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Wound Assessment

DATE: 06/11/2016

Circle the appropriate assessment.

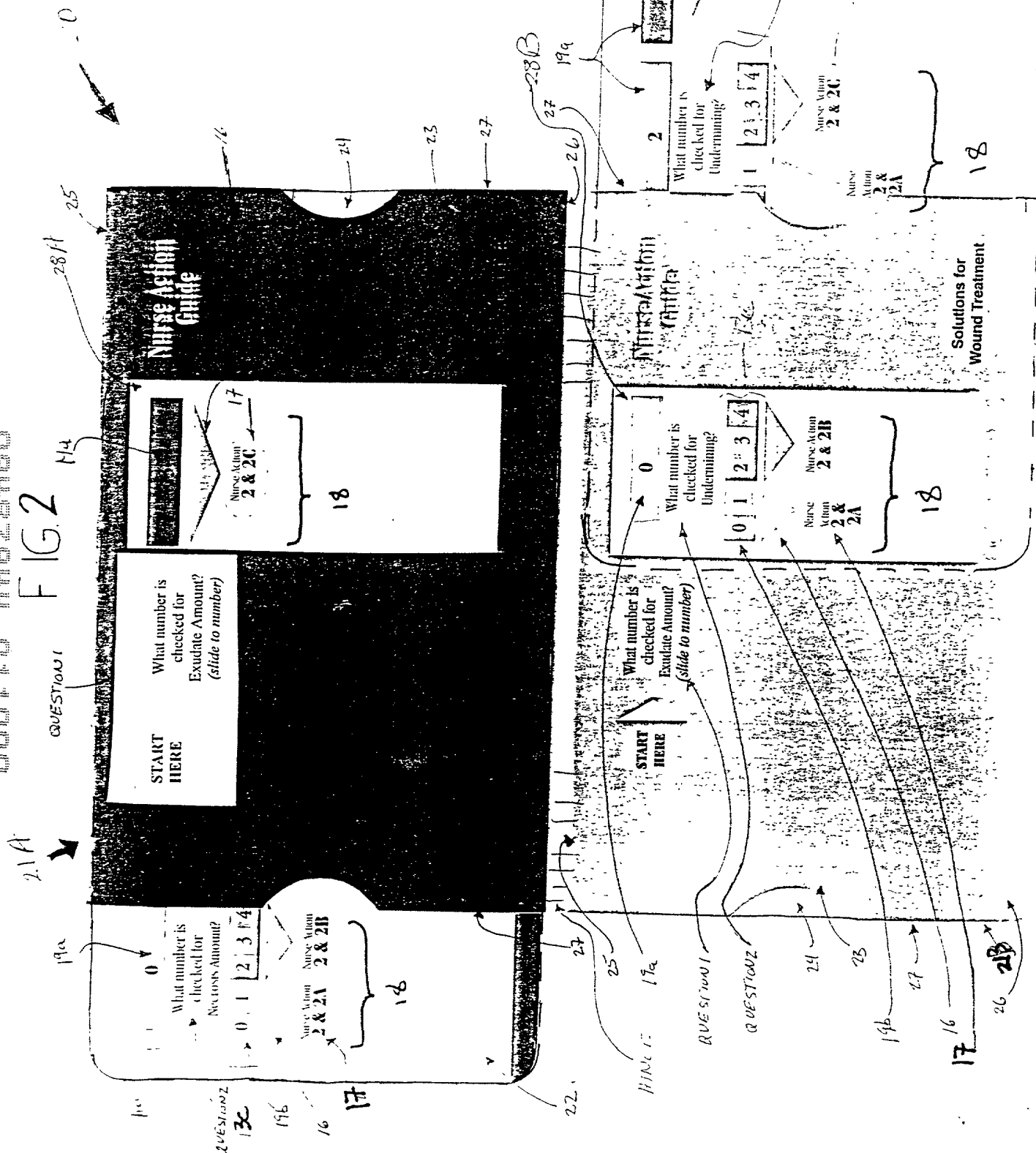
	0	1	2	3	4	5
Classification of Wound	Healed Stage 1	Stage 1 (non-blanchable erythema on intact skin, not resolving within 30 min. of pressure relief) Superficial wound Grade 0 (diabetic foot ulcer) Closed Stage 2, 3, or 4 or first degree burns	Stage 2 (partial thickness skin loss) (abrasion, blister, shallow crater, skin graft donor site, Grade 1 diabetic foot ulcer, or second degree burns)	Stage 3 (penetration to subcutaneous tissue; not past fascia/open surgical wound not past fascia, Grade 2 diabetic foot ulcer, or third degree burns)	Stage 4 (full thickness skin loss with extensive destruction, tissue necrosis, damage to muscle, bone/open surgical wound past fascia, Grade 3 diabetic foot ulcer or third degree burns (4th degree)	Cannot be staged, obscured by necrosis
Exudate Amount	None	Minimal <25% saturation of dressing product per change	Moderate 26-75% saturation of dressing product per change	Heavy >75% saturation of dressing product per change		
Necrotic Tissue Amount	None	<25%	26-50%	51-75%	>75%	
Undermining	None	<2cm in any area	2-4cm involving <50% of wound margins	2-4cm involving >50% of wound margins	>4cm any area	
Color of Tissue Around Wound	Normal for ethnic group	Red +/- blanches to touch	Pale, lack of pigment	Dark red, purple +/- non blanching	Black or hypopigmented	
Granulating Tissue	Skin intact or partial thickness	Beefy red and shiny	Pink	No granulation tissue present		
Peripheral Edema	None around wound	Non-pitting edema in cm	Pitting edema in cm	Crepitus		
Peripheral Induration	0	0 - 1cm	1 - 2cm	2cm or greater		
Pain (or Wound)	0	1 to 2	3 to 4	5 to 6	7 to 8	9 to 10

Worse Pain Intelligible

0 1 2 3 4 5 6 7 8 9 10



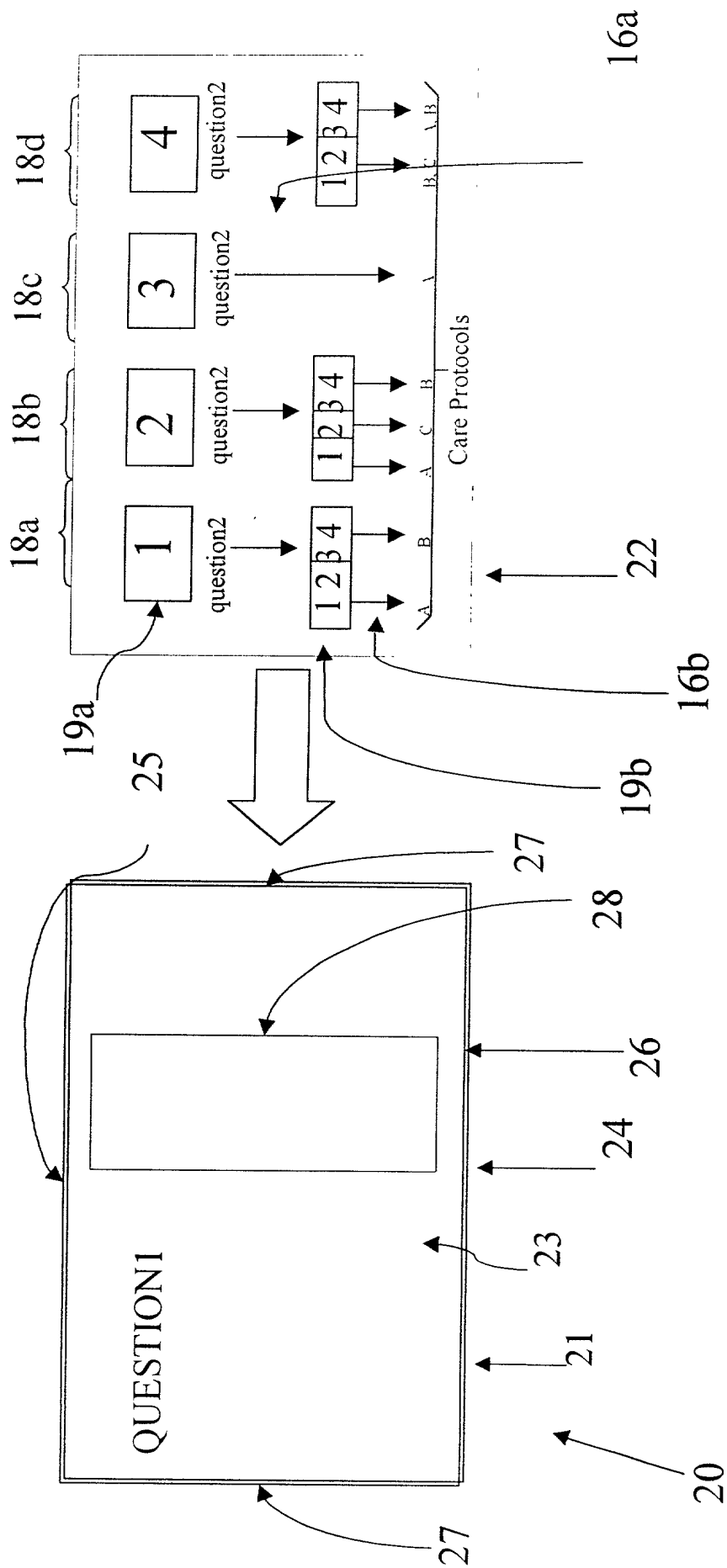
FIG 2





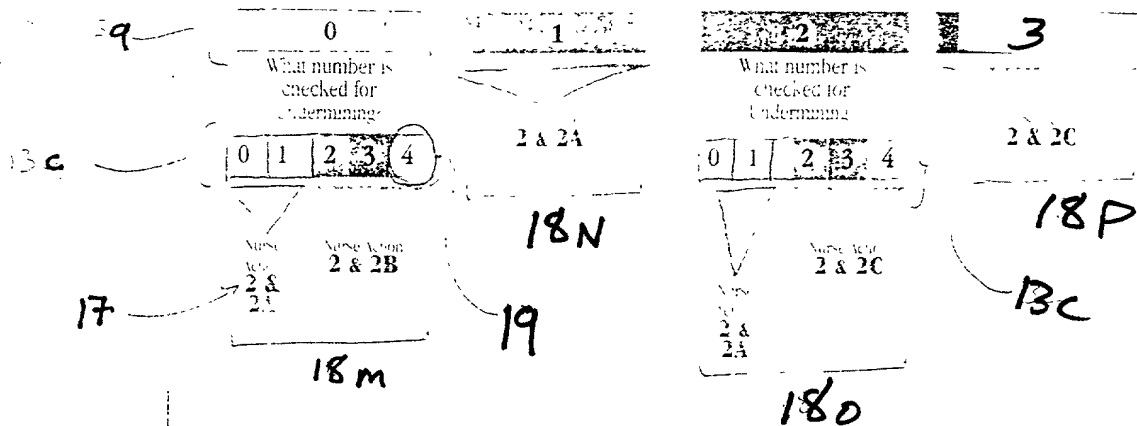
F1525

FIG. 2A

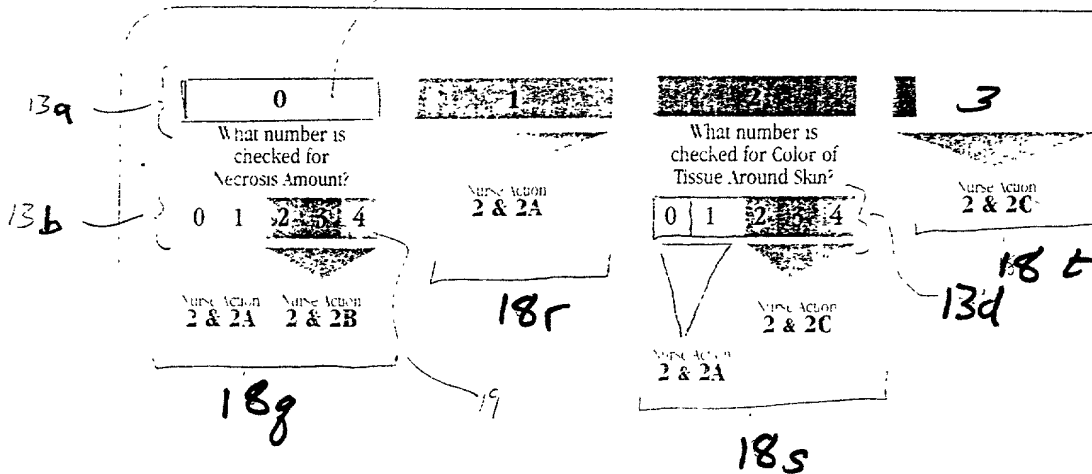


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19a



22a



22b

FILE 20

Patient Risk Assessment Record



Braden Scale

Patient ID

Assessment Date

Clinician

Circle appropriate assessment

Legend



Sensory Perception
Ability to respond meaningfully to pressure-related discomfort

1. Completely Limited
Unresponsive (does not mean, flinch or grasp) to painful stimuli, due to diminished level of consciousness or sedation

2. Very Limited
Responds only to painful stimuli. Cannot communicate discomfort except by moaning or restlessness.

3. Slightly Limited
Responds to verbal commands, but cannot always communicate discomfort or the need to be turned

4. No Impairment
Responds to verbal commands, has no sensory deficit which limits the ability to feel pain or voice pain or discomfort

1 2 3 4
1b 2b 3b



Moisture
Degree to which skin is exposed to moisture

1. Constantly Moist
Skin is kept moist almost constantly by perspiration, urine etc. Dampness is detected every time patient is moved or turned

2. Very Moist
Skin is often, but not always, moist. Linen must be changed at least once a shift

3. Occasionally Moist
Skin is occasionally moist, requiring an extra linen change approximately once a day

4. Barely Moist
Skin is usually dry, linen only requires changing at routine intervals

1 2 3 4

See Moisture Chart



Activity
Degree of physical activity

1. Bedfast
Confined to bed

2. Chairfast
Ability to walk severely limited or non-existent. Cannot bear own weight and/or must be assisted into chair or wheelchair

3. Walks Occasionally
Walks occasionally during the day, but for very short distances, with or without assistance. Spends majority of each shift in bed or chair

4. Walks Frequently
Walks outside the room at least twice a day and inside room at least once every two hours during waking hours

1 2 3 4

See Activity Chart



Mobility
Ability to change and control body position

1. Completely Immobile
Does not even make slight changes in body or extremity position without assistance.

2. Very Limited
Makes occasional slight changes in body or extremity position but unable to make frequent or significant changes independently

3. Slightly Limited
Makes frequent though slight changes in body or extremity position independently

4. Freely Mobile
Makes major and frequent changes in position without assistance

1 2 3 4

See Nutrition Chart



Nutrition
Usual food intake pattern

1. Very Poor
Never eats a complete meal. Rarely eats more than 1/3 of any food offered. Eats 2 servings or less of protein (meat or dairy products) per day. Takes fluids poorly. Does not take liquid dietary supplement

2. Probably Inadequate
Rarely eats a complete meal and generally only about 1/2 of any food offered. Protein intake includes only 3 servings of meat or dairy products per day. Occasionally will take dietary supplement if offered.

3. Adequate
Eats over half of most meals. Eats a total of 4 servings of protein (meat or dairy products) per day. Occasionally will refuse a meal, but usually will take a supplement if offered.

4. Excellent
Eats most of every meal. Never refuses a meal. Usually eats a total of 4 or more servings of meat and dairy products. Occasionally eats between meals. Does require supplementation

1 2 3 4



Friction & Shear

1. Problem
Requires moderate to maximum assistance in moving. Complete lifting without sliding against sheets is impossible. Frequently slides down in bed or chair, require frequent repositioning with maximum assistance. Spasticity, contractures or agitation lead to almost constant friction.

2. Potential Problem
Moves feebly or requires minimum assistance. During a move skin probably slides to some extent against sheets, chair restraints, or other devices. Maintains relatively good position in chair or bed most of the time but occasionally slides down

3. No Apparent Problem
Moves in bed and in chair independently and has sufficient muscle strength to lift up completely during move. Maintains good position in bed or chair at all times

4. Excellent
Eats most of every meal. Never refuses a meal. Usually eats a total of 4 or more servings of meat and dairy products. Occasionally eats between meals. Does require supplementation

1 2 3 4

See Friction & Shear Chart

TOTAL

QUESTION 1



Activity
What number is indicated?
(Slide to number)

1	2	3
Nurse Action K	Nurse Action L	Nurse Action M
Is the Braden Scale total score <13?		
Yes		
Nurse Action J		

Nutrition
What number is indicated?
(Slide to number)




1	2	3	4
Nurse Action P	Nurse Action Q	Nurse Action R	Nurse Action S

Friction & Shear
What number is indicated?












1	2	3	4
Nurse Action T	Nurse Action U	Nurse Action V	Nurse Action X

FIG. 5

0064044-01900

 Oral	 R & S	 Parenteral	 Nurse Action
 Oral	 R & S	 Parenteral	 Nurse Action
 Oral	 R & S	 Parenteral	 Nurse Action

22f

 What number is indicated for sensory perception?	 Nurse Action	 Is the Braden Scale total score < 13?	 Nurse Action
 What number is indicated for sensory perception?	 Nurse Action	 Is the Braden Scale total score < 13?	 Nurse Action
 What number is indicated for sensory perception?	 Nurse Action	 Is the Braden Scale total score < 13?	 Nurse Action

22e

01050

FIG. 6
Nurse Action Report Sheet

Managing Moisture		Managing Moisture		Managing Nutrition	Friction & Shear
A Table 3, Section 1A	E Table 3, Section 1E	G Table 3, Section 2G	K Table 3, Section 2K	O Table 3, Section 3O	
B Table 3, Section 1B	F Table 3, Section 1F	H Table 3, Section 2H	L Table 3, Section 2L	P Table 3, Section 3P	W Table 3, Section 4W
C Table 3, Section 1C	D Table 3, Section 1D	I Table 3, Section 2I	M Table 3, Section 2M	S Table 3, Section 3S	
D Table 3, Section 1D		J Table 3, Section 2J	N Table 3, Section 2N	T Table 3, Section 3T	
				U Table 3, Section 3U	
				V Table 3, Section 3V	

Wound Care Assessment Record

Name _____

Date of Birth _____ Admission Date: _____

Discharge Date: _____

Patient ID _____ Assessment Date _____

Existing Wound ☐ Ulcer # _____

New Wound ☐ Give Ulcer # _____

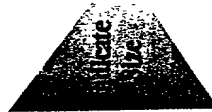
Clinician _____

Coughlin/Waller



Wound Type

- ☐ Arterial/Ischemic Ulcer
- ☐ Burn
- ☐ Neuropathic Ulcer
- ☐ Perineal
- ☐ Dermatitis
- ☐ Pressure Ulcer
- ☐ Rash
- ☐ Skin Tear
- ☐ Surgical Wound
- ☐ Venous Ulcer
- ☐ Other _____



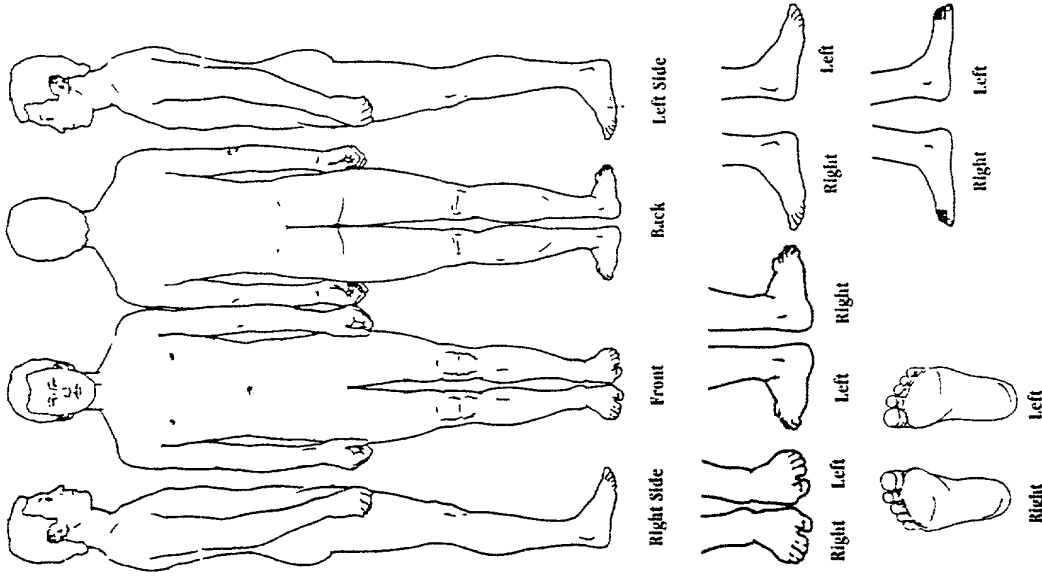
Measurements

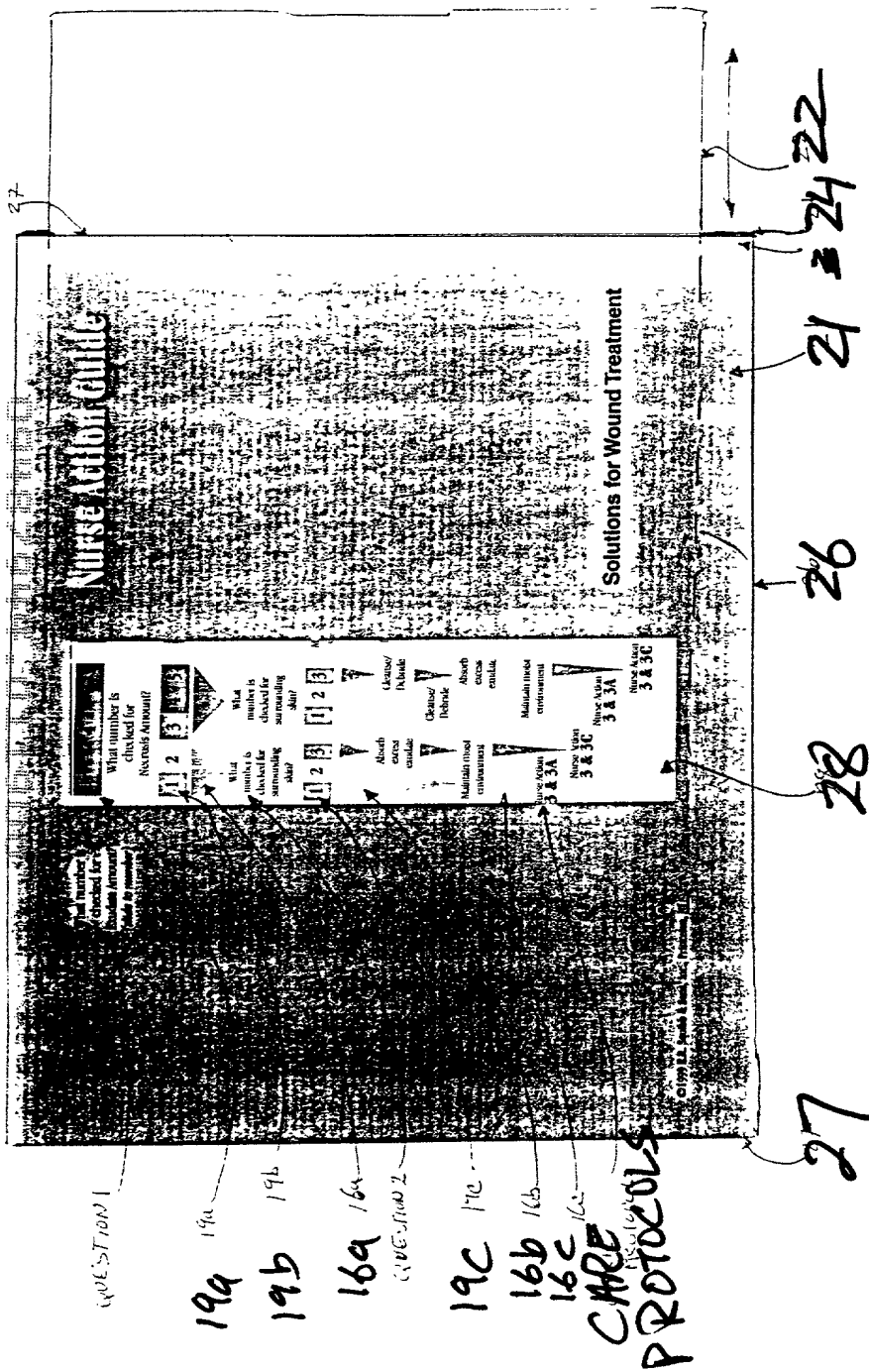
Length = Longest Axis

Length _____ cm
Width _____ cm
Depth _____ cm

Butterfly Only

Length _____ cm
Width _____ cm
Length _____ cm
Width _____ cm
Depth _____ cm





85F

WOUND ASSESSMENT

DATE: 11/6/2016

PRESSURE SULE STATUS (UOI) (P555)

Circle the appropriate assessment.

	Nurse Action 1 and See Blue Side of Nurse Action Guide	See Blue Side of Nurse Action Guide	See Red Side of Nurse Action Guide	Nurse Action 2	See Red Side of Nurse Action Guide	Nurse Action 4	Nurse Action 6
Depth	Non-blanchable erythema on intact skin	Partial thickness involving epidermis & on dermis	Full thickness, damage/necrosis of subcutaneous tissue may extend down to fascia &/or mixed partial full thickness obscured by granulation tissue	Obscured by necrosis	Full thickness with extensive destruction		
Exudate Amount	None	Scant	Small	Moderate	Large		
Exudate Type	None or bloody	Serosanguinous thin, watery, pale red/pink	Serous thin, watery, clear	Purulent thick, opaque, yellow/green with odor	Loose purulent thick, opaque, yellow/green with odor		
Necrotic Tissue Amount	None visible	<25% wound bed covered	25-50% wound covered	>50% wound covered	75-100% wound covered		
Necrotic Tissue Type	None visible	White/gray or non-adherent yellow slough	Loosely adherent yellow slough	Adherent soft black eschar	Firmly adherent, hard black eschar		
Undermining	<2cm in any area	2-4cm <50% of wound margins	2-4cm >50% of wound margins	>4cm in any area	Tunneling or sinus tract infection		
Surrounding Skin Color	Pink or normal for ethnic group	Bright red &/or blanches to touch	White or gray pallor or hyperpigmented	Dark red or purple &/or non-blanchable	Black or hyperpigmented		
Granulation	Skin intact or partial thickness	Bright, beefy red 75%-100% wound filled	Bright, beefy red <75% & >25% wound filled	Pink/dull dusky red &/or fills < 25%	No granulation present		

13a

13b

13c

13d

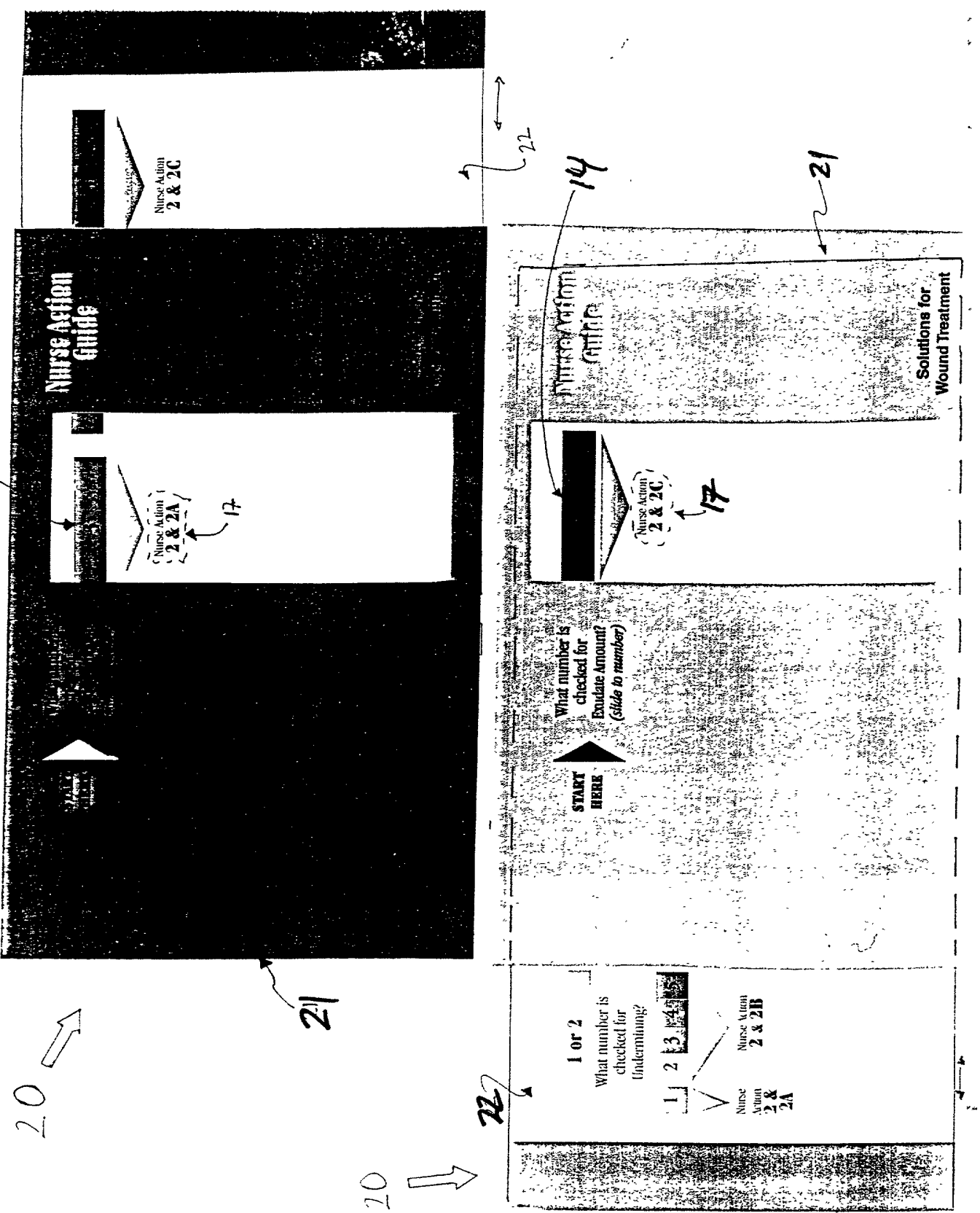
13e

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	Nurse Action 6	No pitting swelling around wound	Minimal swelling around wound	Minimal bruising around wound	No response	Normal	1	2	3	4	5	Nurse Action 5 & 6
Peripheral Edema	Minimal swelling around wound	No pitting <1cm around wound	No pitting <1cm around wound	No pitting <1cm around wound	No pitting <1cm around wound	No pitting <1cm around wound						
Peripheral Induration	Minimal bruising around wound	<2cm around wound	<2cm around wound	<2cm around wound	<2cm around wound	<2cm around wound						
Pain @ Wound	No response	No verbal 1-3	Minimal 4-6	Moderate 7-9	Severe pain 10	Severe pain 10						
Nutrition	Normal	75%	50%	Poor <50%	Tube or poor oral	Tube or poor oral						
Infection	Erythema	1	2	3	4	5						
Edges	Indistinct, diffuse, none visible	Distinct, outline visible, attached, even with base	Well defined, not attached, rolled to base	Well defined, not attached, rolled under thickened	Well defined, fibrotic, scarred or hyperkeratotic	Well defined, fibrotic, scarred or hyperkeratotic						
Epithelialization	100% covered, skin intact	75-100% covered & or extends > 5cm into wound bed	50-75% covered & or extends > 5cm into wound bed	25-50% covered	<25% covered	<25% covered						
Functional Ability	Normal	Slight change	50%	<50%	<25%	<25%						
Compliance	Motivated 100%	Motivated 75%	Motivated <75%	Motivated 50%	Motivated 25%	Motivated 25%						
Healthy Margin	2cm	Yes	No									

How much time spent on assessment?
_____ Minutes

FIG. 10



Patient ID _____

Assessment Date _____

Add New Wound _____

Clinician _____

Caregiver/Writer

Ulcer # _____

Existing Wound _____

Status

- ☐ Active
☐ Healed

Wound Type

- ☐ Arterial/Ischemic Ulcer
☐ Burn
☐ Neuropathic Ulcer
☐ Perineal
☐ Dermatitis
☐ Pressure Ulcer
☐ Rash
☐ Skin Tear
☐ Surgical Wound
☐ Venous Ulcer
☐ Arterial/Ischemic Ulcer
☐ Other _____

Wound Stage

- ☐ Stage I
☐ Stage II
☐ Stage III
☐ Stage IV
☐ Unable to stage
☐ N/A

Wound Site

- ☐ Ankle
☐ Back of Head
☐ Coccyx
☐ Ear
☐ Elbow
☐ Forearm
☐ Heel
☐ Iliac Crest
☐ Ischial Tuberosity
☐ Knee
☐ Lower Leg
☐ Sacrum
☐ Scapula
☐ Thigh
☐ Toe(s)
☐ Trochanter
☐ Vertebrae
☐ Other _____

Wound Shape

- ☐ Butterfly
☐ Irregular
☐ Linear/Elongated
☐ Oval
☐ Square
☐ Round
☐ Rectangle

Measurements

Length = Longest Axis

Length _____ cm
Width _____ cm
Depth _____ cm

Butterfly Only

Length _____ cm
Width _____ cm
Length _____ cm
Width _____ cm
Depth _____ cm

Wound Placement

- ☐ Left
☐ Right
☐ N/A
☐ Anterior
☐ Anterolateral
☐ Inferior
☐ Lateral
☐ Medial
☐ Posterior
☐ Other _____

Factors Delaying Wound Healing

- ☐ Blood Related
☐ Anemia of any sort
☐ Compromised vascular tree (arterial, venous)

Malnutrition

- ☐ Albumin < 3.0g/dl

Deficiencies in:

- ☐ Iron
☐ Protein
☐ Vitamin A
☐ Vitamin C
☐ Water
☐ Zinc

Metabolic Disorders

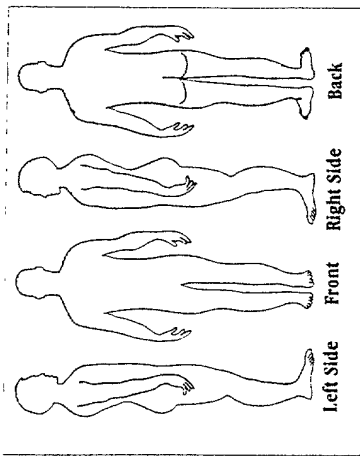
- ☐ Diabetes
☐ Thalassemia

Other

- ☐ Radiation Therapy/Cytotoxic Drugs
☐ Smoking
☐ Stress
☐ Steroids/Anti-Inflammatory Medications
☐ Surgery

Current Primary Diagnosis

Indicate proper area



- FIG 11 -

CV283, drawing elements

- 10** Interactive visual scoring sheet
 - first defined scale **11**
 - first wound factor **12**
 - second defined scale **13**
 - second wound factors **14**
 - criteria **15** pertaining to wound or patient classification
 - connecting indicia **16**
 - treatment protocols **17**
 - visual decision tree **18**
 - markers **19**
- 20** Visual Decision Tree Device
 - housing **21**
 - sliding card **22**
 - top layer **23**
 - bottom layer **24**
 - top edge **25**
 - bottom edge **26**
 - side edge **27**
 - view window **28**
 - first question **QUESTION1**
 - first set of markers **19a**
 - first set of arrows **16a**
 - a second set of markers **19b**
 - second question **QUESTION2**
 - second set of arrows **16b.**
- 30** Wound care protocol sheet
 - module **31**
- 40** Patient data sheet